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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,376	05/19/2004	Dwight Mckee	382/9-1801	6519

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WILLIAM J. SAPONE
COLEMAN SUDOL SAPONE P.C.
714 COLORADO AVENUE
BRIDGE PORT, CT 06605

EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/849,376

Applicant(s)

MCKEE ET AL.

Examiner

Susan D. Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,7 and 10-27 is/are pending in the application.
- 4a) Of the above claim(s) 14-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,7 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The amendment filed April 4, 2005, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 2, 5, 8, and 9 have been cancelled.
3. Claims 1, 3, 4, 6, 7, and 10-27 are pending.
4. In the reply filed on October 20, 2004, applicant elected of Group I and vitamins for species A without traverse.
5. Claims 14-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 20, 2004.
6. Claims 1, 3, 4, 6, 7, and 10-13 are examined on the merits.

Claim Rejections - 35 USC § 112

Claims 1, 3, 4, 6, 7, and 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 is indefinite because the phrase “when the extract contains about 25% acemannan” is confusing in regards to what is required in the claim. Is the 25% concentration of acemannan optional? The amounts for L-glutamine and L-glycine are found after this “when.” Does this mean that the claimed amounts of L-glutamine and L-glycine are only required when the 25% concentration of acemannan is present? For the sake of examination, all of the limitations after the recitation of “when” are considered to be optional. Claim 3 is confusing for

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similar reasons. Is the amount of aloe vera claimed only required when the aloe contains 25% acemannan?

Claim Rejections - 35 USC § 102

8. Claims 1, 4, 12, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. Pub. No. 2003/0084912 A1 in light of CSL website about aloe (<http://web.archive.org/web/200202222223322/http://aloe-vera.com/learnaboutaloe.html>) - February 20, 2002 as evidence of inherency for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the amendments to the claims overcomes this rejection. However, as discussed above, since it is unclear if the limitations after "when" are required limitations, for the sake of examination they are considered optional. Thus, applicant's claim 1 reads on an oral composition comprising 30 to 300 mg of aloe vera extract containing acemannan mixed with L-glutamine, L-glycine, and a pharmaceutically acceptable carrier. US '912 teaches a composition that contains aloe, glycine, glutamine, and vitamins (see claim 5). The composition is in unit dose form (see claim 15) and contains pharmaceutically acceptable carriers. The ingredients are present in amounts from 30 to 100mg (see paragraph 87).

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Claim Rejections - 35 USC § 103

9. Claims 1, 3, 4, 6, 7, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Betterlife.com (www.betterlife.com/prod_home_page.asp?prod_if=7465 (Copyright 2001)), US Pat. No. 5,977,073 and US Pat. No. 6,592,908.

Betterlife.com teaches that a Manapol containing tablet enhances the immune system. The tablet contains 150 mg of Manapol and vitamins. Applicant's specification defines Manapol has an aloe vera extract that contains a concentration of 25% acemannan (see page 3, third paragraph).

US '073 teaches an oral composition that enhances the immune system comprising 50 to 3000 mg of L-glutamine (see column 2, lines 25-38). The composition also contains pharmaceutically acceptable carriers (see column 3, lines 10-11).

US '908 teaches a tablet for enhancing the immune system that contains 150 mg of glycine.

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that enhance the immune system. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

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Based on the disclosure by these references that these substances are used in compositions that enhance the immune system, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to enhance the immune system. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

10. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.


6-8-15
Susan D. Coe
Primary Examiner
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